

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL INDUSTRY	:
AVERAGE WHOLESALE PRICE	:
LITIGATION	: MDL No. 1456
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	: Civ. No. 01-CV-12257 PBS
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	: Hon. Patti B. Saris
THIS DOCUMENT RELATES TO PROPOSED	:
NATIONWIDE CLASSES 2 AND 3 AS TO	:
BMS AND ASTRAZENECA	:
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**ASTRAZENECA PHARMACEUTICAL LP'S MEMORANDUM  
OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO  
CERTIFY NATIONWIDE CLASSES 2 AND 3**

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## **PRELIMINARY STATEMENT<sup>1</sup>**

Plaintiffs' motion to certify a nationwide class action is startling when viewed from each of three perspectives. Each perspective triggers a separate set of basic concerns:

### **The Unspoken Context of the Motion – 7th Amendment**

In August 2005, the Court denied without prejudice the motion for these national classes, which would have been triable by a jury. In the same order, however, the Court sua sponte certified a Massachusetts class; it had not been requested. The Massachusetts class action was not tried by a jury; the Court was the trier. The Court tried that case and found against AstraZeneca. After briefing, the Court made findings and imposed damages (double in some respects) on AstraZeneca and then, at the end of the same order, invited plaintiffs to seek national classes. The fundamental right to a jury trial and protecting it from incursions by trial courts structuring proceedings, has been established since Beacon Theaters, Dairy Queen, and their numerous progeny: jury issues are tried first, and then control non-jury determination, not vice versa. If the national classes, triable by jury, were conceivably certifiable in 2005, then denying certification but sua sponte creating and trying the non-jury Massachusetts class structurally infringed upon AstraZeneca's right to have a jury's factual determinations control the Massachusetts class action. And if the Court now were to certify national classes, the effect of sequencing non-jury and jury proceedings would be completed: non-jury determinations will

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<sup>1</sup> To minimize repetition, AstraZeneca incorporates by reference pertinent memoranda on file with the Court, including: Track 1 Defendants' Memorandum in Opposition to Class Certification (Docket Entry # 1132); Defendant AstraZeneca's Proposed Jury Instructions (Docket # 4146); Defendant AstraZeneca's Memorandum Regarding Class 1 Jury Instructions (Docket Entry # 4033); Defendant AstraZeneca's Motion To Decertify Class 1 (Docket Entry # 3896); Defendant AstraZeneca's Response to Plaintiffs' Memorandum Concerning the Start of the Class 1 Jury Trial and Request for Plaintiffs to Present A Fair and Manageable Trial Plan (Docket Entry # 3816); and AstraZeneca and the joint defendants' proposed findings of fact and conclusions of law for Massachusetts classes 2 and 3. Where applicable to both defendants, AstraZeneca also adopts the arguments in the opposition to this motion filed by BMS.

have been issued first, without the proper effect of jury determinations, and will be argued to have preclusive effect in a subsequent jury proceeding.

**The “Grouping” Facade of the Motion – Rule 23, Stare Decisis**

To obtain Rule 23 certification, Plaintiffs define as their sole task “to group” the consumer protection laws of 38 jurisdictions. Courts have speculated that it might conceivably be possible to group multiple state laws (never so many in any event) for Rule 23 purposes – but no one has heretofore been able to “group” what the Supreme Court called “a patchwork of rules representing the diverse policy judgments of lawmakers in 50 States.” BMW of N. Am., Inc. v. Gore, 517 U.S. 559, 570 (1996). Plaintiffs’ showing, however, is just a lawyer’s jottings of some elements of some aspects of the consumer protection laws of 38 jurisdictions, coupled with a pronouncement that their only “task” for certification – “grouping” – has been accomplished. “Grouping,” as plaintiffs seek to peddle to the Court, just means a list of elements of the statutes or a few case squibs strung together.

**The Substantive Crux of the Motion – Article III, Erie, Rules Enabling Act, the Right to Defend, etc. . .**

Any “grouping” immediately becomes illusory by plaintiffs’ proposed “handling” of the case. Indeed, plaintiffs go far beyond the repeatedly rejected attempts to amalgamate different state laws into an artificial, legal *Esperanto* to be the rule of decision. Plaintiffs, while seeking certification under 38 different consumer protection statutes, propose that a jury decide a hypothetical common law fraud claim – of course no such claim is asserted by the purported classes, raising an immediate “case or controversy” concern that plaintiffs ignore. The result of the jury’s verdict on each of the five elements of common law fraud is somehow to be “applied” to the elements of each jurisdiction’s consumer protection statute. All complexity is removed and a metamorphosis takes place: the parties try, and the jury decides, a non-asserted common

law fraud claim, and AstraZeneca cannot defend against it because the jury does not hear about or decide any consumer protection law claims or defenses.

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The fundamental constitutional and Rule 23-related problems with the national class proposal plaintiffs seek to persuade the Court to embrace cannot be understated. With this Court's bench trial rulings and Rule 54(b) judgment, including class certification issues, on appeal before the First Circuit, the Court's analysis of plaintiffs' national class proposal, if undertaken at all at this point, should take into account the above context, the enormous weight of authority set forth below, as well as the fact that plaintiffs are asking the Court to go out on limb without having even attempted to make the showings required of them under Rule 23, and Supreme Court, First Circuit and this Court's rulings.

## ARGUMENT

### **I. Plaintiffs' Suggestion of Trying a Hypothetical Fraud Claim Under A Restatement Provision Underscores their Inadequate Showing and Would Undermine the Tenets of Rule 23**

After this Court certified classes 2 and 3 under Mass. Gen. Laws ch. 93A, the First Circuit reinforced the view that a district court must rigorously analyze the claims, defenses, relevant facts, and applicable substantive law on a motion for class certification. In re Polymedica Sec. Litig., 432 F.3d at 5-6 (quoting cases in the Third, Fourth, Fifth, Seventh and Eleventh Circuits).<sup>2</sup>

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<sup>2</sup> Over AstraZeneca's objection, this Court avoided application of the "rigorous analysis" requirement to Dr. Hartman's testimony by adopting the "'fundamentally flawed'" standard of review. In re Pharm. Average Whole Sale Price Litig., 230 F.R.D. 61, 87-91 (D. Mass. 2005) (quoting Visa Check/Master Money Antitrust Litig., 280 F.3d 124, 135 (2d Cir. 2001)). The Second Circuit has since repudiated the Visa Check standard. In re IPO Litig., 471 F.3d 24, 40 (2d Cir. 2006) ("Obviously, we can no longer continue to advise district courts . . . that an expert's report will sustain a plaintiff's burden so long as it is not 'fatally flawed.'").

To circumvent the requirement of predominance and in contravention of Polymedica, plaintiffs propose the use of a “common law fraud” standard in the Restatement as a substitute for 38 consumer protection statutes. The Restatement does not reflect the consumer protection law in any jurisdiction, nor even the law of intentional misrepresentation, except where officially adopted by statute or judicial opinion. See, e.g., Black’s Law Dictionary (8th ed. 2004). Neither Rule 23, Erie, the REA, or the Due Process Clause permit this Court to proceed under a fictitious “national consumer protection act.” In re Rhone-Poulenc Rorer, Inc., 51 F.3d 1293, 1300-01 (7th Cir. 1995) (vacating class certification order proposing “Esperanto” instructions that merged various state laws into a single legal standard). A fortiori, this Court cannot adjudicate the case under the Restatement on intentional misrepresentation – an amalgamation that does not accord with the “actual law” of the states under which plaintiffs seek class certification. Id. at 1300; see also In re Stucco Litig., 175 F.R.D. 210, 217 (E.D.N.C. 1997) (a federal district court “must give effect to the variations in state law, however minor they may be”); Harding v. Tambrands Inc., 165 F.R.D. 623, 629-30 (D. Kan. 1996) (same).<sup>3</sup>

Courts have long recognized the “great diversity in the language, scope, degree of enforcement, and judicial interpretation of the various state consumer protection laws.”<sup>4</sup> As discussed in AstraZeneca’s memorandum on jury instructions for class 1 and accompanying jury

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<sup>3</sup> Even were use of the Restatement permissible, predominance and manageability concerns would remain. Clay v. Am. Tobacco Co., 188 F.R.D. 483, 502 (S.D. Ill. 1999) (multi-state action under Restatement would present “a daunting task . . . to determine whether to impose such liability on the defendants for conduct occurring in states that have not considered the issue or have rejected the [Restatement] section altogether.”); Duvall v. TRW, Inc., 578 N.E.2d 556, 560 (Oh. App. 8th Dist. 1991) (affirming denial of class certification where plaintiff failed to provide an “extensive analysis” of state law and “merely state[d] that thirty-nine of the fifty states have adopted Restatement of the Law 2d, Torts (1965) 347, Section 402A, Strict Liability”) (citing federal case law).

<sup>4</sup> Wade v. Jobe, 818 P.2d 1006, 1014 (Utah 1991); BMW, 517 U.S. at 568-69 (CPAs are “a patchwork of rules representing the diverse policy judgments of lawmakers in 50 states”); Tylka v. Gerber Products Co., 178 F.R.D. 493, 498 (N.D. Ill. 1998) (“[A] brief review of the [consumer fraud] statutes reveals not only nuances, but differing standards of proof, procedure, substance, and remedies”).

instructions (Docket Entry #4035), there exist variations under state CPAs relating to: (1) levels of scienter; (2) whether reliance is required and, where required, whether the standard is objective (reasonable), subjective (actual) or elements of both (justifiable); (3) nuances on loss causation; (4) structures ranging from prohibitions on deception, unfairness and/or unconscionability generally to dozens of enumerated provisions, which themselves may be subdivided into categories with limited applications, such as “advertising”; (5) definitions of plaintiffs, e.g., “average,” “unsophisticated” or “least sophisticated” consumer; (6) degrees to which a defendant must be involved in the “transaction” on which the claim is based; (7) a continuum of heightened burdens of proof for exemplary damages; and (8) statute of limitations considerations, including different time periods, repose provisions, and tolling rules.<sup>5</sup>

## **II. Plaintiffs’ Scheme to “Aggregate” Legal Standards Violates the Due Process of Absent Class Members**

According to plaintiffs, this case can be adjudicated under a single common law fraud standard which, if satisfied, “may” constitute a violation of certain CPAs. Even if otherwise an authorized solution to predominance (and manageability) concerns, manipulating state laws to include additional or different elements would violate the due process of each absent class member, whose claim must be judged “according to the law of its jurisdiction, not according to that of a putative or imaginary strictest state.” In re School Asbestos Litig., 977 F.2d 764, 797 (3d Cir. 1992) (suggesting that mandamus would have been an appropriate remedy against prior

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<sup>5</sup> “A few examples of the variations in state law will suffice to illustrate the magnitude of the problem.” In re Ford Motor Co. Vehicle Paint Litig., 182 F.R.D. 214, 223 (E.D. La. 1998); In re Worldcom, Inc., 343 B.R. 412, 428 (Bankr. S.D.N.Y. 2006) (variations in “scienter, reliance, statute of limitations, and proof of injury” defeated both predominance and manageability of nationwide consumer class); see also Southern States Police Benev. Ass’n, Inc. v. First Choice Armor & Equip., Inc., 241 F.R.D. 85, 93 (2007) (limiting certification to claims under chapter 93A because the law under eight additional consumer protection acts varied).

district court judge who certified multistate class action under the “strictest” tort standards) (applying Phillips Petroleum Co. v. Shutts, 472 U.S. 797 (1985)).

Plaintiffs proposed the same unlawful scheme in connection with class 1. See 3/26/07 Tr. 9: 12-14 (“we are taking into consideration . . . ways to heighten the liability requirement . . . in order to be able to aggregate the consumer protection statutes”). But neither the parties nor the Court may broker an “agreement” to amalgamate the requirements of multiple state laws to facilitate predominance. In re School Asbestos Litig., 977 F.2d at 798 (“urg[ing] the incoming district judge to examine Shutts carefully before submitting the case to the jury according to the law of a hypothetical strictest state, even if the class plaintiffs once agreed to that approach”) (emphasis added). As this Court recognized in the class 1 context, without such an unlawful amalgamation, the Court cannot try plaintiffs’ claims on a class-wide basis. Tr. 8:23 (JUDGE SARIS: “we had talked in terms of only essentially a fraud claim going to this jury because the other statutes vary so much”); 9:1-2 (JUDGE SARIS: “we weren’t going to go with any lesser standards because it would be too many questions for the jury”); 16:24-25 (JUDGE SARIS: “I’m not going to ask state-specific questions . . . I think it would overwhelm a jury”).<sup>6</sup>

As discussed below, these legal variations, which must be applied, are further compounded by elements and defenses that require individualized proof.

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<sup>6</sup> While AstraZeneca does not condone the use of a fraud standard in lieu of the applicable statutes, plaintiffs also underestimate variations in the law of intentional misrepresentation. See, e.g., Field v. Mans, 516 U.S. 59, 73-74 (1995) (“Of the 46 States that articulated the required level of reliance in a common-law fraud action, 5 required reasonable reliance, 5 required mere reliance in fact and 36 required an intermediate level of reliance, most frequently referred to as justifiable reliance.”); Rosen v. Chrysler Corp., 2000 WL 34609135, at \*9 (E.D. Mich. July 18, 2000) (not certifying multistate common law fraud class where states had different standards on reliance). Thus, use of a common law fraud standard is not an adequate solution. See, e.g., Kirkpatrick v. J.C. Bradford & Co., 827 F.2d 718, 725 (11th Cir. 1987) (diverse legal standards for common law fraud defeated predominance in proposed nationwide class action).



## A. The Elements of Plaintiffs' Claims Cannot Be Resolved Apart From Circumstances Specific to Each Plaintiff

### 1. Scienter

As apparent from plaintiffs' Exhibits, the "level of scienter" differs among various consumer protection laws. See, e.g., Lyon v. Caterpillar, Inc., 194 F.R.D. 206, 219-21 (E.D. Pa. 2000) (refusing to certify class under 41 CPAs); see also Zapka v. Coca-Cola Co., 2000 WL 1644539, at \*4 (N.D. Ill. 2000) (describing diverse mental state requirements under CPAs). Thus, even if AstraZeneca's alleged deception was a common factual issue, varying standards for scienter create individual legal issues. The other elements of plaintiffs' claims and AstraZeneca's affirmative defenses – which implicate differences in plaintiffs' subjective knowledge and circumstances – present both individual legal and factual issues that compel denial of class certification.<sup>7</sup>

### 2. Reliance

A number of jurisdictions require reliance as an element of their CPAs;<sup>8</sup> others apply a proximate causation standard that is the functional equivalent of reliance.<sup>9</sup> Reliance is an

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<sup>7</sup> See, e.g., Andrews v. AT&T Co., 95 F.3d 1014, 1025 (11th Cir. 1996) ("Even if it could be shown that Appellants were engaged in a scheme to defraud, plaintiffs would still have to show, on an individual basis, that they relied on the misrepresentations, suffered injury as a result, and incurred a demonstrable amount of damages.") (emphasis added). Here, the Court must consider these issues as well as AstraZeneca's affirmative defenses under more than one substantive law.

<sup>8</sup> See, e.g., Kuehn v. Stanley, 91 P.3d 346, 351 (Ariz. App. 2004); Cocca v. Philip Morris Inc., 2001 WL 34090200, at \*3 (Ariz. Super. 2001); Martinez v. Lewis, 969 P.2d 213, 220-21 (Colo. 1998); Finstad v. Washburn Univ., 845 P.2d 685, 688-89 (Kan. 1993); accord Benedict v. Altria Group, Inc., 241 F.R.D. 668, 697 (D. Kan. 2007); Sanders v. Francis, 561 P.2d 1003, 1006 (Or. 1977); accord Pearson v. Philip Morris, Inc., 2005 WL 2840670, at \*5 (Or. Cir. Ct. 2005); Santana Prods., Inc. v. Bobrick Washroom Equip., Inc., 401 F.3d 123, 136 (3d Cir. 2005) (citing Weinberg v. Sun Co., Inc., 777 A.2d 442 (Pa. 2001)); Ind. Code Ann. § 24-5-0.5-4; Schmidt Enterprises, Inc. v. State, 354 N.E.2d 247, 252-53 (Ind. App. 1976); Philip Morris Inc. v. Angeletti, 752 A.2d 200, 235 (Md. 2000); Brookings Municipal Utilities, Inc. v. Amoco Chem. Co., 103 F. Supp. 2d 1169, 1178 (D.S.D. 2000); Daugherty v. Jacobs, 187 S.W. 3d 607, 614 (Tex. App. 2006); Wy. Stat. § 40-12-108 (a); Smith v. Brown & Williamson Tobacco Corp., 108 F. Supp.2d 12, 15-16 (D.D.C. 2000).

<sup>9</sup> See, e.g., Agrella v. Ford Motor Co., 2006 WL 1493823, at \*6 (Conn. Super. Mar. 18, 2006); Stephenson v. Capano Development Inc., 462 A.2d 1069, 1077-78 (Del. 1983); Oliveira v. Amoco Oil Co., 776 N.E. 2d 151,

individual issue that precludes class certification. PolyMedica, 432 F.3d at 7 (absent “efficient market” exception applicable in securities fraud cases “individual questions of reliance would inevitably overwhelm the common ones under Rule 23(b)(3)”; In re Xcelera.com Sec. Litig., 430 F.3d 503, 507 (1st Cir. 2005) (“Individual issues of reliance would necessarily overwhelm the common ones.”); In re IPO, 471 F.3d at 42 (“establishing reliance individually by members of the class would defeat the requirement of Rule 23 that common questions of law or fact predominate over questions affecting only individual members.”). Moreover, the existence of individualized factual and legal issues relating to the extent of reliance on AWP compounds the problem. Fed. R. Civ. P. 23(b)(3) Advisory Committee’s Notes (“a fraud case may be unsuited for treatment as a class action if there was material variation . . . in the kinds or degrees of reliance.”) (emphasis added).<sup>10</sup>

### 3. Causation

Causation, an element under each of the 38 CPAs, raises individual issues. See, e.g., Mulford v. Altria Group, Inc., 242 F.R.D. 615, 629 (D. N.M. 2007) (although plaintiffs were not required to show reliance under the N.M. CPA, loss causation was an individual issue which, together with related affirmative defenses, defeated predominance). Because “knowledge” of the basis for their claims provides a triable defense against plaintiffs, this Court must consider

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153 (Ill. 2002); Hageman v. Twin City Chrysler-Plymouth Inc., 681 F. Supp. 303 (M.D.N.C. 1988); Fink v. Ricoh Corp., 839 A.2d 942, 965 (N.J. Super. 2003); Charleston Lumber Co., Inc. v. Miller Housing Corp., 458 S.E.2d 431, 438 (S.C. App. 1995); Consol. Dairy Prods. Co. v. Bar-T Ranch Dairy, 97 Wash. 2d 167, 180 (1982); K & S Tool & Die Corp. v. Perfection Machinery Sales, Inc., 720 N.W.2d 507, 521 (Wis. App. 2006).

<sup>10</sup> Plaintiffs claim to have satisfied reliance as a matter of law because “Plaintiffs and class members made payments based on AWP.” Even if plaintiffs proved a causal nexus between AstraZeneca’s alleged deception and their losses – which they have not – reliance and, in this context, proximate cause, requires a causal nexus between AstraZeneca’s alleged deception and plaintiff’s decision to enter into the transaction, not merely their losses.

whether causation – in conjunction with other individual issues under multiple state laws – precludes class certification.<sup>11</sup>

Each individual plaintiff will have to show that but for defendants' alleged conduct, i.e., publication of AWP, they would have acted differently. Their ability to do so depends on their own knowledge of the spreads and other facts, which cannot be resolved on a class-wide basis. See, e.g., Int'l Union of Operating Engineers v. Merck & Co., 929 A.2d 1076, 1087 (2007) (causation was a predominating individual issue under N.J. CPA where each TPP, relying on Pharmacy Benefits Managers, made individualized decisions concerning benefits for their members). Under their own theory of the case, plaintiffs have differing "expectations" regarding AWP and subjective business reasons for reimbursing based on AWP.<sup>12</sup> Thus, continued reimbursement or payment based on AWP after learning of the alleged deception provides a defense under the applicable CPAs. See, e.g., Bass v. Prime Cable of Chicago, Inc., 674 N.E.2d 43, 51-52 (Ill. App. 1996) (plaintiff's continued receipt of cable service in additional outlets after discovering deceptive converter charge was a defense under Illinois CPA).<sup>13</sup> On causation (and other individual issues), AstraZeneca is entitled to "cross-examine" each plaintiff. See, e.g.,

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<sup>11</sup> This Court agreed that knowledge and sophistication of class members was important to the parties' claims and defenses, In re Pharm. Indus. Average Wholesale Price Litig., 491 F.Supp.2d 20, 48 (D. Mass. 2007) ("AWP"), but failed to draw the ineluctable conclusion that class treatment was inappropriate. See, e.g., Lewis Tree Serv., Inc. v. Lucent Techs. Inc., 211 F.R.D. 228, 235 (S.D.N.Y. 2002) (variations in "the knowledge and sophistication of purchasers" were predominating individual issues in N.J. CPA action).

<sup>12</sup> While AstraZeneca continues to object to plaintiffs' novel theory, Dr. Hartman's "surrogates" for empirical evidence of actual "expectations" cannot obviate this (or any other) inherently individual issue.

<sup>13</sup> See also Gary Plastic Packaging Corp. v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 903 F.2d 176, 179 (2d Cir. 1990) (affirming denial of class certification where class representative was subject to "several unique defenses including its continued purchases . . . despite having notice of, and having investigated, the alleged fraud"); In re TJX Companies Retail Sec. Breach Litig., 2007 WL 4199597, at \*6 (D. Mass. Nov. 29, 2007) ("evidence of general causation will not suffice to prove the element of causation with regard to fraud-related losses on a class-wide basis" which must be "determined loss-by-loss"); Markarian v. Conn. Mut. Life Ins. Co., 202 F.R.D. 60, 68-69 (D. Mass. 2001) ("Causation is yet another example of the predominance of individualized issues" where the "total mix of information" available to each class member is "distinctive, if not unique").

Arch v. Am. Tobacco Co., Inc., 175 F.R.D. 469, 489 (E.D. Pa. 1997) (denying class certification because the jury would need to determine causation plaintiff-by-plaintiff).

#### 4. Damages

Although issues relating to the “mechanical” determination of damages may not prevent certification of an otherwise appropriate class, Klay v. Humana, Inc., 382 F.3d 1241, 1259-60 (11th Cir. 2004), whether a particular plaintiff in classes 2 or 3 sustained damages at all, and the extent to which each did so, must be determined by reference to whether reimbursements or co-pays were made based on AWP. Thus, case-by-case resolution of whether payments were made based on AWP is a core element of liability. See, e.g., Polion v. Wal-Mart Stores, Inc., 2006 WL 4472492, at \*14 (Mass. Super. Nov. 7, 2006) (“There is a critical distinction . . . between the existence of any harm and the measurement of that harm.”) (emphasis in original). Similarly, a TPP’s alleged damages, if any, depends, in part, on whether their actuaries miscalculated in setting premiums to account for AWP as a benchmark. The federal courts of appeal are unanimous that using “aggregate damages” to resolve individual issues of liability, as proposed here, would “circumvent individualized proof requirements and alter the substantive rights at issue.” Blue Cross and Blue Shield v. Philip Morris USA Inc., 344 F.3d 225-27 (2d Cir. 2003); Broussard v. Meineke Discount Muffler Shops, Inc., 155 F.3d 331, 345 (4th Cir. 1998); In re Fibreboard Corp., 893 F.2d 706, 711 (5th Cir. 1990); Windham v. American Brands, Inc., 565 F.2d 59, 65-66 (4th Cir. 1977); In re Hotel Tel. Charges, 500 F. 2d 86, 89 (9th Cir. 1974).<sup>14</sup>

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<sup>14</sup> Even “calculation” of damages weighs against predominance where, as here, their formulaic determination is not feasible. Corley v. Orangefield Indep. Sch. Dist., 152 Fed .Appx. 350, 355 (5th Cir. 2005) (“where the issue of damages ‘does not lend itself to . . . mechanical calculation, but requires separate mini-trial[s] of an overwhelmingly large number of individual claims,’ class certification will not be appropriate”); Piggly Wiggly Clarksville, Inc. v. Interstate Brands Corp., 215 F.R.D. 523, 532 (E.D.Tex. 2003) (same). Dr. Hartman obscures factual issues in calculating damages by substituting national sales data for actual data on reimbursements and by failing to exclude opt outs or adjusting for transactions not based on AWP. In addition, plaintiffs have not accounted for states, such as Oregon, that prohibit aggregate damages awards. See, e.g., ORCP 32F(2). In any

In addition, as noted in AstraZeneca's class 1 briefing and as apparent from plaintiffs' Exhibits, states have varying substantive and evidentiary standards for imposing punitive damages, which further defeats predominance. In re Baycol Prods. Litig., 218 F.R.D. 197, 215-216 (D. Minn. 2003) (denying class certification where, due to variations in state law, "determination of punitive damages is based on individual issues") (collecting cases)); accord Buynie v. Airco, Inc., 2007 WL 2275013, at \*8 (N.J. Super. Ct. App. Div. Aug. 10, 2007).

**B. The Elements of AstraZeneca's Affirmative Defenses Cannot Be Resolved Apart From Circumstances Specific to Each Plaintiff**

Although not dispositive in themselves, AstraZeneca's affirmative defenses must be considered in the predominance calculus. Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 296 (1st Cir. 2000) ("we regard the law as settled that affirmative defenses should be considered in making class certification decisions"); accord Mulford, 242 F.R.D. at 629-30 (refusing to certify class against manufacturer because, in addition to individualized questions of loss causation, affirmative defenses of statute of limitations and comparative fault "overwhelmed the common issues raised by Defendants' conduct") (applying Mowbray). With multiple state laws applicable to AstraZeneca's defenses, certification would be even more inappropriate. Gartin v. S & M NuTec LLC, 245 F.R.D. 429, 441 (C.D. Cal. 2007) ("Defendant's affirmative defenses of contributory negligence, mitigation of damages, and the statute of limitations 'require an individualized determination for each putative class member because these defenses turn, in large part, on each class member's knowledge and conduct.'") (emphasis added); see also Barnes v. American Tobacco Co., 161 F.3d 127, 149 (3d Cir. 1998) (individual issues relating to comparative negligence and statute of limitations prevented class certification).

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event, the propriety of plaintiffs' statistical "proof" of damages as a basis for class certification is academic because they have insufficient common proof on issues relating to liability.

## 1. Statute of Limitations

Adding to the matrix of individual issues is AstraZeneca's statute of limitations defense. See, e.g., Thorn v. Jefferson-Pilot Life Ins. Co., 445 F.3d 311, 320 (4th Cir. 2006) (statute of limitations determinations would "generally require individual examination of testimony from each particular plaintiff to determine what he knew and when he knew it"); Corley v. Entergy Corp., 220 F.R.D. 478, 487-88 (E.D. Tex. 2004) (in multistate class action, varying statutes of limitations defeated predominance); Labauve v. Olin Corp., 231 F.R.D. 632, 674 (S.D. Ala. 2005) ("The primacy of individual-specific proof considerations is further magnified under the lens of defendants' statute of limitations defense."). As plaintiffs concede in their Exhibits, the 38 states at issue have statutes of limitations ranging from one to ten years, with differing rules on fraudulent concealment and equitable tolling, where even applicable at all. Thus, to determine whether a given statute of limitations bars, in whole or in part, a class members' claim requires individual inquiries into differing degrees of knowledge, at different times, under different substantive laws.

## 2. Comparative Fault and Mitigation

The same analysis applies to comparative fault. Mulford, 242 F.R.D. at 629 n.9 (affirmative defense of comparative fault under Kansas CPA was an individual issue). That certain class members knew of the facts underlying their claims and continued to reimburse or make co-payments supports such a defense here. The "application of comparative fault to the class's claims raises numerous individual issues that prevent a finding of predominance." Emig v. Am. Tobacco Co., Inc., 184 F.R.D. 379, 390 (D. Kan. 1998). Mitigation, another distinct defense under some CPAs, e.g., Gunn Infiniti, Inc. v. O'Byrne, 996 S.W.2d 854, 856 (Tex. 1999)

(“Nothing in the DTPA evidences a legislative intent to withdraw mitigation of damages as an affirmative defense”), further defeats predominance.

### **3. Voluntary Payment Doctrine**

“The voluntary payment doctrine applies to any cause of action which seeks to recover a payment on a claim of right, whether that claim is premised on a contractual relationship or a statutory obligation.” Harris v. ChartOne, 841 N.E.2d 1028, 1031 (Ill. Ct. App. 2005). As applied to an action under the Illinois CPA, “[t]he voluntary payment doctrine is a corollary to the mistake of law doctrine and, in its general formulation, holds that a person who voluntarily pays another with full knowledge of the facts will not be entitled to restitution.” Randazzo v. Harris Bank Palatine, N.A., 262 F.3d 663, 667 (7th Cir. 2001). Because plaintiffs have different levels of knowledge and sophistication, whether their claims are subject to the voluntary payment defense is another individual issue further defeating predominance. See, e.g., Solomon v. Bell Atlantic Corp., 9 A.D.3d 49, 55 (2d. Dep’t 2004) (in CPA action, reversing certification of class against DSL internet service providers in part because the “voluntary payment” doctrine would “bar recovery by any subscriber who, having experienced slow service and/or frequent connectivity outages, continued to use defendants’ DSL service”).

### **III. Plaintiffs’ Failure to Submit a Feasible Trial Plan Reinforces the Fundamental Flaws In their Proposed Class Action**

Under Rule 23(c)(1)(B), plaintiffs must propose a trial plan explaining how the claims and defenses discussed above can be resolved on common factual evidence under various legal standards. Fed. R. Civ. P. 23(c) Advisory Committee Notes; Wachtel v. Guardian Life Ins. Co.

of Amer., 453 F.3d 179, 189 (3d Cir. 2006) (trial plan and class certification order must in a “clear and cogent form, define the claims, issues, or defenses to be treated on a class basis”).<sup>15</sup>

Under the pretence of “grouping” and proposing a “trial plan,” plaintiffs seek to adjudicate common law fraud claims in 38 jurisdictions under the Restatement and then, by some to-be-announced process, have this hypothetical mock trial extrapolated to actual claims under actual consumer protection statutes, or at least some portions thereof. The law is plain that any proposed “grouping,” however, must not “amalgamate” differing legal standards in order to reduce manageability problems at the expense of federal law and constitutional imperatives. In re Bridgestone/ Firestone, Inc., 288 F.3d 1012, 1020 (7th Cir. 2002) (“Differences across states may be costly for courts and litigants alike, but they are a fundamental aspect of our federal republic and must not be overridden in a quest to clear the queue in court.”).<sup>16</sup> Nor may grouping deprive defendant of a fair opportunity to challenge each individual on the elements of his claim or to interpose affirmative defenses. Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154, 192 (3d Cir. 2001) (defendant entitled “to raise individual defenses against each class member” under Rule 23 and due process); Elec. Co. v. Stern, 544 F.2d 1196, 1199 (3d Cir. 1976) (same); Kline v. Coldwell Banker & Co., 508 F.2d 226, 236 (9th Cir. 1974)

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<sup>15</sup> See also Allison v. Citgo Petroleum Corp., 151 F.3d 402, 420 n.15 (5th Cir. 1998) (denial of certification appropriate because of plaintiffs’ failure to provide “any workable plan”); Valentino v. Carter Wallace, Inc., 97 F.3d 1227, 1234 (9th Cir. 1996) (deeming it an abuse of discretion to certify where the plaintiffs failed to show how the proposed class action could be tried); Castano v. American Tobacco Co., 84 F.3d 734, 740 (5th Cir. 1996) (reversing certification decision that failed to assess “how a trial on the merits would be conducted”).

<sup>16</sup> See also Cimino v. Raymark Indus., Inc., 151 F.3d 297, 312 (5th Cir. 1998) (“[U]se of Rule 23(b)(3) . . . does not alter the required elements which must be found to impose liability and fix damages (or the burden of proof thereon) or the identity of the substantive law . . . which determines such elements.”).



(same); see also Pujol v. Shearson Am. Exp., Inc., 877 F.2d 132, 134 (1st Cir. 1989) (class certification must be consistent with due process).<sup>17</sup>

Plaintiffs provide “absolutely no guidance regarding an orderly manner in which to apply all the varying states’ laws.” Sweet v. Pfizer, 232 F.R.D. 360, 370-71 (C.D. Cal. 2005); see also Cole v. Gen. Motors Corp. 484 F.3d 717, 725-26 (9th Cir. 2007) (showing “textual similarities of each jurisdiction’s applicable law” does not satisfy plaintiffs’ burden on a motion to certify a multistate class action). Because plaintiffs propose a “composite” legal standard and jury instructions for adjudicating the parties’ individual legal and factual disputes, they lack “an adequately detailed and reasonable plan showing how this case can be managed given . . . the varying effects of local law in [multiple] jurisdictions on each such claim.” Oxford v. Williams Cos., 137 F. Supp. 2d 756, 764 (E.D. Tex. 2001); In re Ford Motor Co. Ignition Switch, 174 F.R.D. 332, 350 (D. N.J. 1997) (same); see also In re Prempro, 230 F.R.D. 555, 568 (E.D. Ark. 2005) (“The absence of an adequate trial plan and proper jury instructions supports what Defendants have said all along – there is no way that the claims of these multi-state plaintiffs can be adequately addressed in a single class action trial.”). Without an adequate trial plan and coherent jury instructions on the elements of plaintiffs’ claims (e.g., deception, reliance, causation, damages) and to AstraZeneca’s affirmative defenses (e.g., statute of limitations, comparative fault, mitigation, voluntary payment doctrine), “there is no manageable method by which to handle the individual issues that defendant is entitled as a due process matter to raise in

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<sup>17</sup> The Supreme Court has clarified recently that a Court may not impose punitive damages under state law unless defendant had “an opportunity to present every available defense.” Philip Morris USA v. Williams, 127 S.Ct. 1057, 1063 (2007) (vacating punitive damages award where “a defendant threatened with punishment for injuring a nonparty victim ha[d] no opportunity to defend against the charge, by showing, for example . . . that the other victim was not entitled to damages because he or she knew [the basis for her claim] or did not rely upon the defendant’s statements to the contrary.”) (emphasis added). Because plaintiffs propose collectivizing individual issues relating to liability, any punitive damages award to these classes would be a “plastic number” that violates due process. Jaraslowicz v. Engelhard Corp., 724 F. Supp. 294, 299-300 (D. N.J. 1989).

this case.” Davies v. Philip Morris U.S.A., Inc., 2006 WL 1600067, at \*4 (Wash. Super. May 26, 2006) (consumer class action not manageable where individualized elements and defenses predominated over any common issue of deception).<sup>18</sup> In sum, “Plaintiffs have . . . offered no jury instructions or verdict forms to overcome the manageability difficulties posed by this action.” Chin v. Chrysler Corp., 182 F.R.D. 448, 461 (D.N.J. 1998).<sup>19</sup>

#### **IV. Plaintiffs Have Not Established Adequacy or Typicality**

Even if the proposed classes were otherwise proper, plaintiffs would have to show that the named plaintiffs are typical and adequate representatives. Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 629 (1997). These “due process” requirements find expression in Rule 23(a)(2) and (3). General Telephone Co. of Southwest v. Falcon, 457 U.S. 147, 158 n.13 (1982)

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<sup>18</sup> Plaintiffs also fail to account for the degree to which a TTP or consumer must have engaged in a transaction with AstraZeneca under a particular CPA. See, e.g., Christopher v. First Mut. Corp., 2006 U.S. Dist. LEXIS 2255, 8-12 (D. Pa. 2006) (requiring direct contact with defendant to state a CPA claim); Amstadt v. U.S. Brass Corp., 919 S.W. 2d 644, 649 (Tex. 1996) (“[W]e are not persuaded that the Legislature intended the DTPA to reach upstream manufacturers and suppliers when their misrepresentations are not communicated to the consumer”). Nor have they addressed CPA-specific affirmative defenses, such as “exemption.” See, e.g., Burton v. William Beaumont Hosp., 373 F. Supp. 2d 707, 720-721 (D. Mich. 2005) (Michigan CPA inapplicable to conduct concerning medical billing because the “health care industry is highly regulated by state and federal law.”)

<sup>19</sup> See also In re Paxil Litig., 212 F.R.D. 539, 546 (C.D. Cal. 2003) (“The completed picture will no doubt be too vast and too complicated for even the most diligent jury to grasp”); In re Ford Motor Co. Ignition Switch, 194 F.R.D. 484, 490 (D. N.J. 2000) (“[T]he practicalities of applying such varied state law would demand significant attention from this Court, not the least of which would be instructing the jury or juries consistent with the law of each relevant state”); Lyon, 194 F.R.D. at 221 (E.D. Pa. 2000) (“If I find plaintiff’s jury instructions confusing, how can I expect a lay jury to wade through these questions?”); Cunningham v. PFL Life Ins. Co., 1999 WL 33656879, at \*6 (N.D. Iowa, Aug. 25, 1999) (“The Court believes that trying a case with such disparate legal questions is inefficient, impractical, and will most likely confuse the jurors”); In re Masonite Corp. Hardboard Siding Prods. Liab. Litig., 170 F.R.D. 417, 423-24 (E.D. La. 1997) (“plaintiffs have not shown the Court that it is possible to give one negligence instruction which would account for all the varying nuances that state lawgivers command”); Smith v. Brown & Williamson Tobacco Corp., 174 F.R.D. 90, 98 (W.D. Mo. 1997) (“neither party can seriously expect a jury’s full attention in consideration for the length of such proceedings, nor can they expect evenhanded, consistent treatment from beginning to end”); Ford Motor Co., 174 F.R.D. 332, 350 (D. N.J. 1997) (multistate instruction impossible without “overwhelming jurors with hundreds of interrogatories and a verdict form as large as an almanac”); Harding, 165 F.R.D. at 632 (D. Kan. 1996) (“The jury instructions and verdict form . . . would be extremely complicated given these numerous differences in the law applicable to the various claims”); Carpenter v. BMW of North America, Inc., 1999 WL 415390, at \*6 (E.D. Pa. June 21, 1999) (plaintiffs presented “no plan as to how the jury could meaningfully be instructed on the laws of each jurisdiction with respect to plaintiff’s multiple claims, each of which contains numerous elements, multiplied by thousands of class members”). While not proposed by plaintiffs, AstraZeneca notes that bifurcation of elements or defenses relating to liability would violate the Seventh Amendment’s Reexamination Clause. See, e.g., In re Rhone-Pouenc, 51 F.3d at 1302-03.

(typicality and adequacy requirements “tend to merge” into fairness); In re Am. Med. Sys., Inc., 75 F.3d 1069, 1082 (6th Cir. 1996) (interests of representatives and absentees must be “aligned”). Because class representatives must act through class counsel, adequacy of representation turns on “the competency of class counsel” and on the absence of “conflicts of interest.” Int’l Union v. Gen. Motors Corp., 497 F.3d 615, 626 (6th Cir. 2007); Blaine v. Smithkline Beecham Corp., 240 F.R.D. 179, 189 (E.D. Pa. 2007) (“divergent interests and circumstances will impair the plaintiffs’ ability to adequately protect the interests of the class members”). Further, “to have the requisite typicality to represent a class, a named plaintiff must have individual standing to assert the claim.” Piazza v. Ebsco Indus., Inc., 273 F.3d 1341, 1351 (11th Cir 2001). On the current record, legal and factual conflicts preclude a finding of adequacy or typicality and, as noted below, at least two representatives lack standing, which increases the burden on plaintiffs to show that the remaining ones are sufficient.<sup>20</sup>

**A. Variations in State Law Undermine “Structural Assurances” of A Fair Litigation**

Plaintiffs’ provide no “structural assurance of fair and adequate representation for the diverse groups and individuals affected.” Amchem, 521 U.S. at 627. Where, as here, laws of varying stringency on the parties’ elements and defenses would not guarantee absent class members fair representation, courts have denied class certification. In re Ford Motor Co., 177 F.R.D. 360, 368 (E.D. La. 1997) (“problems are created by the variations in the laws of the fifty-one jurisdictions . . . and the fact that the named plaintiffs’ residences are confined to nine of the

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<sup>20</sup> Although plaintiffs’ motion must be denied on the current record, AstraZeneca would have been entitled to depose PMBT and others possessing additional information on the adequacy and typicality of the proposed representatives. See generally, McLaughlin on Class Actions § 3:7 (2007). AstraZeneca also notes that many of the representatives in both classes have not provided data showing reimbursement for PADs.

fifty-one jurisdictions”); Daly v. Harris, 209 F.R.D. 180, 190 (D. Hi. 2002) (named plaintiffs lacked incentive to litigate against statute of limitations defense on behalf of absentees).

## **B. Factual Class Conflicts Compound the Problem**

### Class 2

Plaintiffs have not explained how UFCW and SMW Health Fund may represent TPPs from 38 states with legal requirements of varying stringency. Moreover, UFCW had long known that AWP was a “benchmark . . . like the suggested retail price . . .” (Segal 136:12-16; Friedman Dep. at 27:1-4) and “doctors were making a margin” (Kaplan 197: 11-12). UFCW’s claim is, therefore, meritless under Illinois (and other states’) laws. Oliveira v. Amoco Oil Co., 776 N.E. 2d 151, 163 (Ill. 2002) (“a plaintiff asserting a claim of deceptive advertising under the Act must prove that he was deceived by that advertising in order to establish proximate causation.”)

### Class 3

Ms. Wessels is not typical, has no claim, does not understand the litigation, and, in her absence, Class 3 lacks a consumer representative:

(a) having paid for Zoladex no earlier than mid-2004 (Wessels Dep. 23:18-24:9; 76: 8-12), Ms. Wessels is differently situated from plaintiffs with pre-2004 claims who may have a lower burden of proof, AWP, 491 F. Supp.2d at 103 (limiting liability of AstraZeneca to 1998-2002 period);<sup>21</sup>

(b) nor can she show “proximate causation” after conceding that she was not deceived by AWP (39:2-14; 42:6-7) and her claim is time-barred based on constructive notice of AWP by mid-2004, Monotype Imaging, Inc. v. Bitstream, Inc., 2005 WL 936882, at \*10 n.11 (N.D. Ill.

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<sup>21</sup> AstraZeneca respectfully disagrees with the Court’s finding of liability for any time period.

2005) (noting relevance of plaintiff's "constructive knowledge" to statute of limitations defense under Illinois CPA);

(c) she had breast cancer (28:22-29:2) and appears to be acting for her insurer, BCBS, not consumers who used the drug for prostate cancer (49:16-50:9);

(d) she may have a claim against UCFW, a more "sophisticated" representative in the same class with knowledge of AWP before 2004, supra; Cromer Fin. Ltd. v. Berger, 205 F.R.D. 113, 126 (S.D.N.Y. 2001) (noting absence of conflict "because class members do not have . . . claims against each other");

(e) she does not understand the nature of the claims asserted in this litigation (20:7-20), Lau v. Arrow Fin. Servs., LLC, 2007 WL 1502118, at \*6 (N.D. Ill. May 22, 2007) (deposition supported finding of adequacy where plaintiff was "familiar with the facts of the case"); and

(f) once Ms. Wessels is excluded for any of these reasons, Class 3 will be limited to entities, which cannot represent individual consumers, In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 532 (3d Cir. 2004) (finding of adequacy affirmed where class had representatives from among TPPs and consumers) and, if not excluded, she would be required to have separate counsel, id. at 533 (noting "existence of separate counsel" for TPPs and consumers).

Man-U Service Fund and PFTHW – neither of which reimburses for Zoladex – have no claim against AstraZeneca or standing to represent another class member. 6/3/04 Brecht Dep. Tr. 49:19-50: & 10/15/04 Merritt Depo. Tr. 57:19 to 58:22 (Man-U); 3/11/04 Steinberg Depo Tr. 122:10 to 123: 15; 6/18/04 Steinberg Depo. Tr. 443:21 to 445: 2; 472:16 to 473:2 (PFTHW).

Zenith – CMHV's third party administrator – admittedly knew that AWP was only a benchmark as early as 1993. (Rhodes Dep. 42:10-43:1; 45:12-20; Bell Dep. 33:8-9; 39-40; 50:19-51:16). Thus, for the same reasons that Wessels cannot represent consumers with

potential claims prior to mid-2004, CMHV should not represent entities claiming a lack of knowledge from 1998-2002.

THWF apparently reimbursed for only three Zoladex claims (Einhorn Dep. 93:5-12). Under the Pennsylvania CPA, THWF must prove the elements of common law fraud, including “justifiable reliance.” Toy v. Metropolitan Life Ins. Co., 928 A.2d 186, 201-03 (Pa. 2007). Given the low number of transactions coupled with the comparatively more stringent legal standards applicable to THWF’s claims, THWF is not an adequate class representative for entities with larger claims under more liberal CPAs.

### CONCLUSION

For the foregoing reasons, plaintiffs’ motion for class certification should be denied.<sup>22</sup>

Dated: January 4, 2008

Respectfully submitted,

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<sup>22</sup> Plaintiffs have neither briefed nor satisfied the requirements for injunctive relief. For the reasons stated in the memorandum of the Track 2 defendants in opposition to plaintiffs’ motion for class certification, HCFA does not have standing and any alleged need for injunctive relief has become moot.

**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered on January 4, 2008 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

/s/ Katherine B. Schmeckpeper

Katherine B. Schmeckpeper